

Appl. No. : 09/931,836  
Filed : August 16, 2001

### REMARKS

After entry of the foregoing amendments, Claim 23 has been amended. Claim 23 has been amended to correct a typographical error in which the word "or" was repeated twice. Thus, no new matter has been added. Claims 27-29 and 32 have been cancelled. The specific change to amended Claim 23 is shown above with the ~~deletion shown stricken through~~. Therefore, Claims 22-26 and 33-34 remain present for examination.

Applicants gratefully acknowledge the withdrawal of the previous objections and objections which were addressed in Applicants' previous response filed on June 12, 2003. Applicants respond below to the specific rejections raised by the Examiner in the Office Action of August 20, 2003.

#### Discussion of Rejections under 35 U.S.C. § 102(e)

Claims 22-29 and 32-34 were rejected under 35 U.S.C. § 102(e) as being anticipated by Piddington et al., U.S. Patent No. 6,521,233 (referred to hereafter as "Piddington"). In the Office Action, the Examiner asserts that Piddington discloses the polypeptide having the sequence of SEQ ID NO:2, and that the functional limitation recited in the claims is an inherent property of the claimed compositions of matter.

In addition, Piddington does not anticipate Claims 22-26 and 33-34 because Piddington fails to enable one of skill in the art to make and use the claimed invention.

A claim can only be anticipated by a reference if the publication describes the claimed invention with sufficient enabling detail to place the public in possession of the invention. *See In re Donohue*, 766 F.2d 531, 533 (Fed. Cir. 1985); *see also PPG Industries, Inc. v. Guardian Industries Corp.*, 75 F.3d 1558, 1566 (Fed. Cir. 1996); *Elan Pharmaceuticals, Inc. v. Mayo Foundation for Medical Education and Research*, 346 F.3d 1051 (Fed. Cir. 2003) ("To serve as an anticipating reference, the reference must enable that which it is asserted to anticipate." "Enablement requires that 'the prior art reference must teach one of ordinary skill in the art to make or carry out the claimed invention without undue experimentation.'"); *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1354 (Fed. Cir. 2003) ("A claimed invention cannot be anticipated by a prior art reference if the allegedly anticipatory disclosures cited as prior art are not enabled."); *PPG Industries, Inc. v. Guardian Industries Corp.*, 75, F.3d 1558,

Appl. No. : 09/931,836  
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1566 (Fed. Cir. 1996) (“To anticipate the reference must also enable one of skill in the art to make and use the claimed invention.”).

Recently, the Federal Circuit Court of Appeals reversed and remanded a district court summary judgement finding the claims invalid under 35 U.S.C. § 102 because the district court failed to consider whether the cited prior art reference was enabling. *See Elan Pharmaceuticals, Inc. v. Mayo Foundation for Medical Education and Research*, 346 F.3d 1051 (Fed. Cir. 2003) (decided October 2003). The district court had determined that the claims were inherently disclosed by the prior art reference, and therefore, were invalid under § 102. *See id.* However, the Federal Circuit reversed that finding of invalidity under § 102 stating that the issue was “more properly characterized as enablement arguments rather than inherency arguments.” *Id.* Thus, the Federal Circuit stated that “[t]o serve as an anticipating reference, the reference must enable that which it is asserted to anticipate.” *Id.*

Here, the Office Action states that Piddington anticipates because it inherently discloses the functional limitation of the claims. However, for the following reasons, Applicants respectfully assert that Piddington does not anticipate because it fails to enable the claims.

The instant application claims priority from PCT Application No. PCT/US00/05601, filed on March 12, 2000. Piddington was filed on April 19, 2000, and claims priority from U.S. Provisional Application No. 60/130,199 (referred to hereafter as “the Piddington provisional application”), filed on April 20, 1999. Thus, for Piddington to anticipate, the Piddington provisional application must enable the claims.

Respectfully, Applicants assert that the Piddington provisional application fails to teach one of ordinary skill in the art how to make and use invention of Claims 22-26 and 33-34 without undue experimentation. Claims 22-26 and 33-34 as set forth above recite isolated polypeptide variants which have the ability to induce chondrocyte redifferentiation. The Piddington provisional application does not teach one of ordinary skill in the art how to make and use these variant polypeptides that have the ability to induce chondrocyte redifferentiation.

The Piddington provisional application does not recognize the ability of any isolated polypeptides to induce chondrocyte redifferentiation, nor does it disclose assays for determining chondrocyte redifferentiation. Therefore, the Piddington provisional application does not and cannot teach how to make and use the claimed isolated variant polypeptides. It follows that the Piddington provisional application does not anticipate the claimed subject matter.

Appl. No. : 09/931,836  
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Thus, Piddington does not anticipate Claims 22-26 and 33-34, because the Piddington provisional application does not provide sufficient detail to teach one of ordinary skill in the art to make and use the claimed isolated polypeptides and chimeric polypeptides having the disclosed function.

Applicants, therefore, request that the Examiner reconsider and withdraw the rejections based on 35 U.S.C. § 102(e).

### CONCLUSION

Applicants have endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action. Accordingly, amendments to the claims, the reasons therefor, and arguments in support of the patentability of the pending claim set are presented above. In light of the above amendments and remarks, reconsideration and withdrawal of the outstanding rejections is specifically requested. If the Examiner finds any remaining impediment to the prompt allowance of these claims that could be clarified with a telephone conference, the Examiner is respectfully requested to initiate the same with the undersigned.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: 11/20/03

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